UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA *ex rel.* BROOK JACKSON, Plaintiff, - v - VENTAVIA RESEARCH GROUP, LLC; PFIZER INC.; ICON PLC, Defendants.	CASE NO. 1:21-CV-00008-MJT **ORAL ARGUMENT REQUESTED**

ICON PLC'S MOTION TO DISMISS RELATOR'S AMENDED COMPLAINT AND MEMORANDUM OF LAW IN SUPPORT

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Defendant ICON plc ("ICON") respectfully moves, pursuant to the Federal Rules of Civil Procedure 9(b) and 12(b)(6), to dismiss Counts I and II of the operative complaint (the "Amended Complaint"), which Plaintiff-Relator Brook Jackson ("Relator") filed on behalf of the United States under 31 U.S.C. § 3730(b), the *qui tam* provision of the False Claims Act ("FCA"). ICON joins and incorporates by reference Defendant Pfizer Inc.'s ("Pfizer") Motion to Dismiss Relator's Amended Complaint and Memorandum of Law in Support [Dkt. No. 37] ("Pfizer's Motion").

PRELIMINARY STATEMENT

It is not at all clear why ICON is a defendant in this False Claims Act litigation. ICON did not submit any claim for payment or otherwise seek or receive any payment from the United States related to vaccine trials. Nor did ICON employ Relator. Instead, the Amended Complaint and its exhibits show that in performing its role providing outsourced monitoring and related services to Pfizer for the trials, ICON identified concerns and worked with the relevant teams to address and ameliorate them as the study progressed.

In this context, it comes as no surprise that Relator falls far short of pleading ***any*** viable claim against ICON. Relator's few allegations against ICON appear to be nothing more than an afterthought and do not come close to stating a claim under the FCA. In fact, by Relator's own allegations, ICON was frequently kept in the dark and even lied to about the alleged misconduct she claims (without any factual basis) that others supposedly engaged in. Nonetheless, and because she clearly views the legal process as nothing more than an avenue to publicize her anti-vaccination political views, Relator instead falls back on shameless and wild speculation, claiming that her experience at two trial sites in Texas for less than three weeks brings the entire

Pfizer BioNTech worldwide vaccine clinical trial into question. These allegations are archetypal examples of those that a court must straight away reject for multiple reasons.

First, Relator's allegations fail to meet the heightened pleading standards of Federal Rule of Civil Procedure 9(b) that all FCA claims must satisfy. The few allegations against ICON are generalized, conclusory, or speculative, and cannot state a claim with the particularity required by Rule 9(b). Relator repeatedly and generically asserts that ICON missed "red flags" of trial protocol violations and that errors would have been obvious from source documents, but fails to state with particularity which red flags ICON allegedly missed, how the alleged violations were supposedly obvious to ICON, the identity of the alleged source documents that would have shown such alleged violations, or how and when ICON received or reviewed the alleged source documents. Many of Relator's allegations are plainly contradictory, as the Amended Complaint is littered with contrary allegations that information was purposefully withheld from ICON and even attaches as exhibits e-mails that show ICON was not ignoring issues with the trial but actively identifying them to Ventavia Research Group, LLC ("Ventavia") and working to resolve them.

Second, the Amended Complaint fails to adequately allege what the Fifth Circuit has termed the *sine qua non* of an FCA claim: a claim requesting money or property from the United States that is either factually or legally false. Relator does not identify ***any*** false claims made to the government by ***any*** Defendant. The most Relator can come up with as to ICON is that it certified and submitted a Statement of Investigator under FDA Form 1572. But government payment was not conditioned on this form (which was not even required to be submitted), nor does Relator sufficiently allege that the form was material to the government's decision to make

a payment. For these reasons, both of Relator's two FCA claims (Counts I and II) against ICON must be dismissed.

Finally, Relator fails to adequately allege another necessary element of an FCA claim: that ICON ***knowingly*** submitted a false statement to the government. Not only does the Amended Complaint not allege that ICON had actual knowledge of the alleged violations of trial protocol, it alleges that this supposed falsity was actively hidden from ICON. Relator alternatively makes conclusory assertions that ICON had constructive knowledge of these allegations, but without the specificity of "who, what, when, where, and how" that is required to avoid dismissal.

For all of these reasons, as well as the reasons stated in Pfizer's Motion, which ICON joins and incorporates by reference herein, and as discussed more fully below, the Court should dismiss Counts I and II of the Amended Complaint with prejudice.[1]

FACTUAL BACKGROUND[2]

ICON is an Irish-headquartered clinical research organization, providing consulting, clinical development, and commercialization services to pharmaceutical, biotechnology, medical device, and public health organizations as well as government agencies. ICON offers services at all phases of clinical development and approval, functional outsourcing assistance, and laboratory services including high value testing.[3]

At the onset of the COVID-19 pandemic, ICON was engaged by Pfizer to implement its strategic plan and framework for the monitoring of the landmark study. ICON helped monitor

[1] Count III of the Complaint is against Defendant Ventavia only and does not involve ICON.

[2] ICON refers the Court to the Factual Background section of Pfizer's Motion, *see* Pfizer's Mot. at 5-18, and states additional factual background relating to ICON specifically herein.

[3] For purposes of this Rule 12(b)(6) motion only, "ICON" refers to ICON plc and/or its relevant subsidiaries. ICON reserves all rights and defenses with respect to the identity of the correct parties.

trials, recruit trial participants, organize clinical supply management services, and provide site training, document management, and informed consent support.[4] The two Ventavia sites that employed Relator were among the 153 sites that ICON worked with in the United States, Europe, South Africa, and Latin America.

It is unclear from the Amended Complaint to what extent (if any) Relator—who only worked at Ventavia for less than three weeks (Am. Compl. ¶¶ 20, 263)—interacted with ICON or ICON personnel. Relator attaches three exhibits to the Amended Complaint, however, that show ICON personnel providing guidance to and asking questions of Ventavia personnel as part of its oversight of the landmark study and its responsibility to ensure clinical trial protocol compliance and required information reporting:

- On September 5, 2020, ICON personnel were told via e-mail by a Ventavia employee that a subject had returned a positive pregnancy test between receiving her first and second vaccinations. (Am. Compl. Ex. 12). The e-mail was forwarded internally to Relator.
- On August 14, 2020, an ICON employee e-mailed a Ventavia employee with a lengthy bulleted list of items, including *inter alia* informing Ventavia that various Ventavia personnel needed to review certain documents or complete certain trainings, noting that certain records were missing, and telling Ventavia to correct certain transcription errors. (Am. Compl. Ex. 16). The e-mail was forwarded internally to Relator.
- Between August 26 and September 21, 2020, ICON personnel sent Ventavia personnel (including Relator) a series of e-mails raising issues regarding missing documentation

[4] "ICON Supports Pfizer and BioNTech on the investigational COVID-19 vaccine trial," ICON, Jan 4, 2021, https://www.iconplc.com/news-events/press-releases/icon-pfizer-biontech/.

and suggesting revising documentation procedures to avoid these issues in the future. (Am. Compl. Ex. 19).

The Amended Complaint describes events that Relator allegedly witnessed during her less-than-three-week stint of employment at Ventavia in September 2020, during which time the Pfizer landmark study was ongoing and Ventavia was under contract to conduct the study at three sites in Texas. (Am. Compl. ¶¶ 49-50). While working at two of these sites, Relator allegedly observed a range of compliance violations by Ventavia, including failures to properly manage trial enrollment, documentation blinding, informed consent procedures, vaccinator training, post-vaccine monitoring of subjects, reporting of adverse events, and other documentation practices. (Am. Compl. ¶¶ 148-205).

Despite these dramatic claims, however, Relator's allegations as to ICON are sparse. Relator asserts that ICON "turned a blind eye to Ventavia's misconduct, despite numerous warning signs," failed to "follow up on missing information," ignored "red flags" of protocol violations and false data, and failed to "exclude ineligible participants from the trial data." (Am. Compl. ¶¶ 6, 9). Relator repeatedly claims that ICON had "constructive notice" of Ventavia's alleged misconduct, because it had access to information "hidden away" by Ventavia in "notes to the file" or "source documents." (Am. Compl. ¶¶ 8, 169, 191). Relator also alleges that ICON failed to follow up on and report adverse event information and to secure Ventavia's compliance after learning of Ventavia's alleged regulatory and protocol violations. (Am. Compl. ¶¶ 211, 213, 214-16).

Relator also relies on the Statement of Investigator under Form FDA-1572, which ICON submitted to Pfizer and in which ICON agreed to "(1) conduct the trial in accordance with the protocol and FDA regulations; (2) obey informed consent and IRB [Institutional Review Board]

reporting requirements; (3) report adverse events; (4) ensure that all 'associates, colleagues, and employees assisting in' the trial were 'informed about their obligations;' and (5) make no changes to the trial without IRB approval." (Am. Compl. ¶ 277). Relator conclusorily asserts that "[t]his acknowledgement and certification was rendered false by . . . ICON's violations of the clinical trial protocol, FDA regulations, and fraudulent conduct." (Am. Compl. ¶ 277).

In addition, and despite conceding that her experience with the Pfizer landmark study "is limited to Texas" and spanned only a manner of weeks, Relator charges that "Pfizer and ICON's oversight failures and fraudulent misconduct vis-à-vis Ventavia bring the entire Pfizer-BioNTech clinical trial into question." (Am. Compl. ¶ 11). Relator also brazenly speculates, with no basis for support whatsoever, that "[i]t is likely that similar fraud occurred at clinical trial sites managed by other subcontractors of Pfizer." (Am. Compl. ¶ 11).

LEGAL STANDARD

When deciding a motion to dismiss under Rule 12(b)(6), a court must accept as true all factual allegations in the complaint but is "not bound to accept as true a legal conclusion couched as a factual allegation." *Aschcroft* v. *Iqbal*, 129 S. Ct. 1937, 1950 (2009).[5] The complaint must contain enough specific factual allegations to show that if all of the alleged facts—and only the alleged facts—are believed to be true, the plaintiff would have a claim for relief. *See Iqbal*, 129 S. Ct. at 1952. Indeed, the pleading must do more than "merely create[] a suspicion [of] a legally cognizable right of action." *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 555, 555-56 (2007). A district court must "insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed . . . into discovery when there is no reasonable

[5] Unless noted otherwise, emphasis is added and internal citations and quotation marks omitted.

likelihood that the plaintiffs can construct a claim from the events related in the complaint." *Id.* at 558.

A complaint that fails to proffer "enough facts to state a claim to relief that is plausible on its face" should be dismissed. *See Twombly*, 550 U.S. at 570. If the factual allegations are so general that they "do not permit the court to infer more than a mere possibility of misconduct," then the plaintiff "[has] not nudged [its] claims across the line from conceivable to plausible." *See Iqbal*, 129 S. Ct. at 1951; *Twombly*, 550 U.S. at 570. Similarly, "a pleading that offers 'labels and conclusions' or a 'formulaic recitation of the elements of a cause of action will not do.'" *Iqbal,* 129 S. Ct. at 1949. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949 (citing *Twombly,* 550 U.S. at 555). When ruling on a motion to dismiss under Rule 12(b)(6), a court may consider public records, including publicly filed financial statements, pleadings from other cases, "materials that do not contradict the complaint, or 'materials that are necessarily embraced by the pleadings.'" *See Noble Systems Cora.* v. *Alorica Central, LLC,* 543 F.3d 978, 982 (8th Cir. 2008); *Henson* v. *CSC Credit Servs.,* 29 F.3d 280, 284 (7th Cir. 1994).

In addition, because FCA claims are fraud actions, the heightened pleading requirements of Rule 9(b) apply. *United States ex rel. Thompson* v. *Columbia/HCA Healthcare Corp.*, 125 F.3d 889, 903 (5th Cir. 1997). Rule 9(b) provides that, "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The circumstances that must be pled with particularity are "the time, place, and contents of the false representation[], as well as the identity of the person making the misrepresentation and what that person obtained thereby." *United States ex rel. Grubbs* v. *Kanneganti*, 565 F.3d 180, 188 (5th

Cir. 2009). "The particularity demanded by Rule 9(b) is supplemental to the Supreme Court's . . . interpretation of Rule 8(a) requiring 'enough facts [taken as true] to state a claim to relief that is plausible on its face." *Id.* at 185. A plaintiff must state the factual basis for the fraudulent claim with particularity, and she cannot rely on speculation or conclusory allegations. *See Thompson*, 125 F.3d at 903. "A dismissal for failure to plead fraud with particularity under Rule 9(b) is treated as a dismissal for failure to state a claim under Rule 12(b)(6)." *Id.* at 901; *Grubbs*, 565 F.3d at 185 n.8.

ARGUMENT

I. THE AMENDED COMPLAINT FAILS TO SATISFY RULE 9(b)'S PLEADING STANDARDS AS TO ICON

In order to survive dismissal, Relator's two causes of action against ICON under the FCA must comply with the heightened pleading standards of Rule 9(b). It does not do so—not even close. For a plaintiff to adequately allege FCA claims under Rule 9(b), she must allege "as to ***each individual defendant*** 'the nature of the fraud, some details, [and] a brief sketch of how the fraudulent scheme operated, when and where it occurred, and the participants.'" *Hernandez* v. *CIBA-GEIGY Corp. USA*, 2000 WL 33187524, at *5 (S.D. Tex. 2000) (quoting *Askanase* v. *Fatjo*, 148 F.R.D. 570, 574 (S.D. Tex. 1993)). The Fifth Circuit has emphasized that it applies Rule 9(b) to FCA claims "with bite and without apology." *United States ex rel. Porter* v. *Magnolia Health Plan, Inc.*, 810 Fed. Appx. 237, 240 (5th Cir. 2020). And courts in the Fifth Circuit have also recognized that "because of the potential for relators to reap a phenomenal windfall and the attendant risk of abuse by professional relators . . . more is required of the *qui tam* relator than almost any other litigant in federal court." *United States ex rel. Ruscher* v. *Omnicare, Inc.,* 2014 WL 2618158, at *33 (S.D. Tex. 2014), *on reconsideration in part sub nom*. *Ruscher* v. *Omnicare Inc.,* 2014 WL 4388726 (S.D. Tex. 2014). Relator's claims against

ICON, based entirely on a handful of generic and conclusory allegations and unsupported speculation, do not even pass muster under the more liberal pleading standard of Rule 8(a)(2), let alone the exacting standard of Rule 9(b). Accordingly, Relator's claims against ICON must be dismissed.

The Amended Complaint alleges nothing of substance against ICON. ICON is treated as a bit player throughout the Amended Complaint, and the small number of allegations of misconduct as to ICON specifically are all generalized, conclusory, or speculative.[6] For example, the Amended Complaint alleges that ICON "failed to follow up on missing information, ignored 'red flags' of trial protocol violations and false data, and failed to exclude ineligible participants from the trial data." (Am. Compl. ¶ 9). But the Amended Complaint does not offer specific details of the alleged red flags or falsified data—the necessary "who, what, when, where, and how" of the allegations. *Thompson*, 125 F.3d at 903. The Amended Complaint also bluntly asserts that Ventavia's alleged violations "would be obvious from the source documents" and that ICON ignored them (Am. Compl. ¶¶ 11, 169), without explaining how the violations actually would have been "obvious."

Indeed, while ICON is rarely mentioned in the 29 separate exhibits filed with the Amended Complaint, when ICON ***is*** mentioned, the exhibits reflect ICON personnel not ***ignoring*** instances of missing information or potential violations of protocol, but actively following up and working with Ventavia personnel to ***correct*** them. (Am. Compl. Exs. 12, 16, 19); *see United States ex rel. Riley* v. *St. Luke's Episcopal Hosp.*, 355 F.3d 370, 377 (5th Cir.

[6] The Amended Complaint's allegations are so lacking that it is not even clear that Relator has identified the correct ICON corporate entity to name as a defendant; instead, the Amended Complaint generically asserts misconduct against the Irish parent company ICON plc, "an Irish company headquartered in Dublin." (Am. Compl. ¶ 45).

2004) ("If an allegation is contradicted by the contents of an exhibit attached to the pleading, then indeed the exhibit and not the allegation controls.").

Finally, at times, the Amended Complaint even veers into wild speculation, such as when Relator baselessly theorizes that "Pfizer and ICON's oversight failures and fraudulent misconduct vis-à-vis Ventavia bring the entire Pfizer-BioNTech clinical trial into question," despite only having experience at two of the Pfizer vaccine study's 153 testing sites and with fewer than 1,000 of the study's 44,000 participants. (Am. Compl. ¶ 11). Allegations like these are, if anything, textbook examples of the kind of pleading that Rule 9(b) expressly prohibits.

II. THE AMENDED COMPLAINT FAILS TO STATE A CLAIM AGAINST ICON UNDER SECTION 3729(a)(1)(A) OF THE FALSE CLAIMS ACT

In the Fifth Circuit, a relator must satisfy four elements to state a cause of action under the FCA: "(1) a false statement or fraudulent course of conduct; (2) that was made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money (i.e., that involved a claim)." *United States ex rel. Spicer* v. *Westbrook*, 751 F.3d 354, 365 (5th Cir. 2014) (quoting *United States ex rel. Longhi* v. *United States,* 575 F.3d 458, 467 (5th Cir. 2009)). A false or fraudulent claim is the "*sine qua non*" of a qui tam action, *Grubbs*, 565 F.3d at 188, and to satisfy this element, a relator must identify a claim requesting money or property from the United States that is either factually or legally false. *United States ex rel. Ruscher* v. *Omnicare, Inc.*, 663 Fed. App'x 368, 373 (5th Cir. 2016). Relator's Amended Complaint fails to satisfy these elements.

A. Relator Does Not Adequately Allege that Any Defendant Made a False or Fraudulent Claim for Payment

Relator does not allege that ICON submitted any claim requesting payment from the United States, let alone a false one. At most, Relator alleges that ICON certified in Form FDA-1572, submitted to Pfizer and the United States, that the trial would be conducted in accordance

with trial protocol and FDA regulations, which was allegedly "rendered false by . . . Icon's violations of the clinical trial protocol, FDA regulations, and fraudulent conduct." (Am. Compl. ¶ 277). But this is not, as is discussed further *infra* II.B, a claim for payment nor was it a false or fraudulent one.

The only claims for payment that Relator alleges are invoices submitted by Pfizer to the government. Relator alleges that Pfizer submitted "legally false" invoices to the U.S. Department of Defense (DoD) because they contained "express and implied false certifications" of compliance with FDA regulations and FAR provisions. (Am. Compl. ¶¶ 274, 278). But, as is discussed in further detail in Pfizer's Motion, the Amended Complaint fails to plead that these invoices contained false claims, because the government's decision to pay was not predicated on Pfizer's compliance with FDA regulations and FAR provisions. *See* Pfizer Mot. at 20-25.

B. Relator Does Not Show that ICON Presented, or Caused to be Presented, a False or Fraudulent Claim

Even if Relator had adequately alleged that the FDA regulations and FAR provisions applied, the Amended Complaint is nonetheless bereft of any facts to sufficiently allege that ICON made a false or fraudulent claim.

Section 3729(a)(1)(A) of the FCA prohibits "knowingly present[ing], or caus[ing] to be a presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(a); *see also United States ex rel. Graves* v. *ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 495 (S.D. Tex. 2003) (noting that a key question under the FCA is "whether the defendant presented a 'false or fraudulent claim' to the government."). Other "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA." *Thompson*, 125 F.3d at 902. The FCA attaches liability "not to the underlying fraudulent activity or the government's wrongful payment, but to the claim for payment." *Longhi,* 575 F.3d at 467. A "claim" is "any request or demand, whether

under a contract or otherwise, for money or property . . . [that] is presented to an officer employee, or agent of the United States . . . ." 31 U.S.C. § 3729(b)(2). The "linchpin" of an FCA claim resting on an alleged violation of a statute or regulation is a "certification of compliance." *Spicer*, 751 F.3d at 365. According to the Fifth Circuit, if "the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely [expressly or impliedly] certifies compliance with that statute or regulation." *Id*. (quoting *United States ex rel. Marcy* v. *Rowan Cos., Inc.,* 520 F.3d 384, 389 (5th Cir. 2008)). According to the U.S. Supreme Court, implied false certification is when a "defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement…that the defendant knows is material to the Government's payment decision." *Universal Health Servs., Inc.* v. *United States*, 579 U.S. 176, 181 (2016).

Here, Relator's sparse allegations against ICON are, if anything, suggestive only of lawful conduct, and do not state a plausible claim that ICON submitted a false statement or caused another Defendant to do so. At no point in Relator's 80-page Amended Complaint or the more than 300 pages of exhibits she appended to it does she allege that ICON presented any claim to the U.S. government. Instead, Relator alleges that ICON certified and submitted a Form FDA 1572. (Am. Compl. ¶ 277). But a Form 1572 is not a claim for payment, nor does Relator even allege that it is. While the Amended Complaint alleges that the "sponsor [i.e., Pfizer] must obtain a signed Form FDA 1572 from each contract investigator [i.e., ICON]," and "[e]ach contract investigator also commits in Form FDA-1572 to promptly report to the IRB 'all changes in the research activity and all unanticipated problems involving risks to human subjects or

others," it does not allege that either the sponsor or the investigator must submit the form to the FDA or that the investigator must report the "changes" or "unanticipated problems" to the FDA. (Am. Compl. ¶ 62); *see also United States ex rel. Gross* v. *AIDS Rsch. All.-Chicago*, 415 F.3d 601, 603-04 (7th Cir. 2005) (dismissing FCA claim relating to filing of FDA Form 1572 where complaint failed to allege that defendants "made a statement in order to receive money from the government"). Nor does Relator allege that ICON's certification of the form somehow caused another Defendant to subsequently submit a false claim for payment.

Relator instead attempts to rely merely on unspecified allegations of fraudulent conduct by ICON, yet the FCA attaches liability "not to the underlying fraudulent activity . . . but to the claim of payment." *Longhi*, 575 F.3d at 467; *see also Gross*, 415 F.3d at 603-04 ("False claim allegations must relate to actual money that was or might have been doled out by the government based upon actual and particularly-identified false representations."). But even if allegations of underlying fraudulent conduct were a sufficient basis for FCA claims, Relator's allegations fall far short of what is required to plead any kind of fraud by ICON. Relator describes ICON as having an oversight role over the clinical trial, and while she baselessly alleges that ICON was negligent in its role and engaged in "oversight failures and fraudulent misconduct vis-à-vis Ventavia" (Am. Compl. ¶¶ 11, 213, 215-16), her sparse allegations do not support this claim. For example, Relator makes many conclusory claims that ICON in some way "turned a blind eye" to misconduct, failed to follow up on missing information, or ignored "red flags." (Am. Compl. ¶¶ 6, 9, 151, 87). But there are vanishingly few actual examples of this in the Amended Complaint, and when there are, they are pled generically and without the requisite specificity.

As an example of one of these ignored so-called "red flags," Relator alleges that, in violation of trial protocol, Ventavia treated women who had undergone tubal ligation as non-

WOCBPs (women of child-bearing potential). Relator alleges that this violation would have been "obvious from the source documents" and ICON ignored them. (Am. Compl. ¶ 151). But Relator does not allege ***why*** this violation would have been obvious or ***how*** ICON ignored it. Indeed, in the referenced exhibit, this issue is flagged as a "QC [Quality Control] Finding" and follow-up is requested. (Am. Compl. Ex. 11 at 3) ("Page 9 source 'childbearing potential and contraception method have been verified' is initialed but checked no for uring preg (sic) not done and that it's 'n/a.' ***Please confirm which is correct- patient had tubal litigation per source***."). This is precisely the type of oversight ICON was engaged to perform, and exactly the type of monitoring activity that is typical of any clinical trial performed on large scale.

Relator also suggests that ICON ignored informed consent dates that were allegedly falsified by Ventavia and did not match dates in source documents that ICON had access to. (Am. Compl. ¶¶ 168-69). But, as an e-mail chain attached as Exhibit 19 demonstrates, ICON did identify these errors, properly flagged them to Ventavia, and recommended remedial actions. (Am. Compl. ¶ 169, Ex. 19). In a parenthetical citing to this exhibit, Relator even describes ICON as "noting informed consent date errors." (Am. Compl. ¶ 169). Relator also alleges that "[m]any clinical trial participants were given their second injection outside of the protocol-mandated nineteen to twenty-three day window," another alleged red flag that ICON supposedly missed, even though "Ventavia never reported this violation to . . . ICON," because "it would have been obvious from the source documents." (Am. Compl. ¶ 176). But Relator once again does not state with sufficient particularity or specificity what ICON missed, why it was "obvious," or the identity of the source documents.

While ICON is generally not mentioned in the 300 pages of exhibits attached to the Amended Complaint, in the small number of documents that do reference ICON, ICON

personnel are shown asking proper questions and providing guidance to Ventavia regarding the clinical trial. (Am. Compl. Exs. 12, 16, 19). For example, an e-mail sent on August 14, 2020, labeled Exhibit 16, reflects an ICON employee properly raising multiple issues for Ventavia to review and fix, as the Amended Complaint itself concedes. (Am. Compl. ¶ 196) ("Ventavia also failed to document improper dilution of the frozen BNT162b2 vaccine concentrate. Defendant Icon noticed the issue and informed Ventavia"). Similarly, in a series of e-mails sent between August 26 and September 21, labeled Exhibit 19, ICON personnel flagged issues with blood collection documentation, including explaining the applicable protocol and FDA requirements and suggesting revisions to Ventavia's documentation to better collect this information. Relator once again concedes that this Exhibit shows ICON properly doing its job. (Am. Compl. ¶ 191) ("Icon also directly questioned missing blood collection and processing times on September 21, 2020 in an e-mail to Fisher, Downs, Relator and others."). These exhibits if anything only make clear the insufficiency of Relator's claims against ICON. *See Braden* v. *Wal-Mart Stores, Inc.,* 588 F.3d 585, 597 (8th Cir. 2009) (finding that "[a]n inference pressed by the plaintiff is not plausible if the facts he points to are precisely the result one would expect from lawful conduct in which the defendant is known to have engaged").

C. Relator Does Not, and Cannot, Allege that ICON's Certification and Acknowledgment of FDA Form 1572 Was Material to the Government's Payment Decision

Even if ICON's certification and submission of Form 1572 had been a "certification of compliance" and a claim for payment, which it was not, Relator does not allege that Form 1572 was material to the Government's payment decision. For a statement to be material, according to the Supreme Court, it must have "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Universal Health Servs., Inc.*, 579 U.S. at 182; *see also Longhi*, 575 F.3d at 470 (holding that for a statement to be material it must "(1) make

the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even if this is a result of indirect or intangible actions on the part of the Defendants."). As the Supreme Court has recognized, the FCA "is not 'an all-purpose antifraud statute,'. . . or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. . . . What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Universal Health Servs., Inc.,* at 182. This is a "demanding standard," *id.*, and the Amended Complaint fails to meet it.

Relator alleges that ICON's acknowledgment and certification of Form 1572 was "rendered false" by subsequent "violations of the clinical protocol, FDA regulation, and fraudulent conduct." (Am. Compl. ¶ 277). Relator neglects to mention that investigators are not required to submit the form to the FDA.[7] A form that is not even required plainly cannot be material. Even if this form were required for payment, the Amended Complaint does not allege that it was material to the government's decision. In fact, the Amended Complaint does not allege that ICON engaged in any affirmative act in the presentation of any claim to the government, much less any false claim. As is discussed further in Pfizer's Motion, the

[7] *See* "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs," U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION, May 2010, https://www.fda.gov/media/78830/download (According to FDA Form 1572, FAQ 6, "Does 1572 need to be submitted to the FDA? No. Although the sponsor is required to collect the 1572 from the investigator, FDA does not require the form to be submitted to the agency. Many sponsors submit the 1572 to FDA, however, because it collects, in one place, information that must be submitted to FDA under 21 CFR 312.23(a)(6)(iii)(b)").

Government's actions since becoming aware of Relator's actions make clear that none of the alleged false statements, either in the Form 1572 or anything else allegedly submitted to the Government, were material to its decision to make payments. *See* Pfizer Mot. at 23-25.

III. THE AMENDED COMPLAINT FAILS TO STATE A CLAIM AGAINST ICON UNDER SECTION 3729(a)(1)(B) OF THE FALSE CLAIMS ACT

For the same reasons as above, Relator's Count II against ICON under Section 3729(a)(1)(B) also fails. While Section 3729(a)(1)(A) prohibits "knowingly present[ing] a false or fraudulent claim" to the government, Section 3729(a)(1(B) prohibits "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim…for the purpose of getting a false or fraudulent claim paid by the Government." *United States* v. *Abundant Life Therapeutic Servs. Texas, LLC*, 2019 WL 1930274, at *6, 9 (S.D. Tex. 2019) (finding that "[a] relator alleging a § 3729(a)[(1)(B)] violation must still show the who, what, when, where, and how of the alleged fraud under Rule 9(b))."). Claims under Section 3729(a)(1)(A) are commonly called "presentment" claims, while those under Section 3729(a)(1)(B) are commonly called "false statement claims." *Id*. Subsection (a)(1)(B) contains a "double falsity" requirement—the relator must plead "both a false statement and a corresponding false claim." *United States ex rel. Silver* v. *Omnicare, Inc.,* 2020 WL 7022664, at *6 (D.N.J. 2020). As explained above, *supra* II.B, Relator does neither. The Amended Complaint does not adequately allege that ICON made any false statements, much less submitted or took part in the submission of a false claim. *See also* Pfizer Mot. at 25-27.

IV. THE AMENDED COMPLAINT FAILS TO ALLEGE THAT ICON ACTED WITH REQUISITE KNOWLEDGE

Even if the Amended Complaint did properly allege that ICON made false statements or submitted a false claim, Relator's FCA claims against ICON would still require dismissal because Relator has failed to adequately allege that ICON knowingly or recklessly did so. A

relator must adequately allege that a defendant "had (1) actual knowledge of falsity, (2) acted with deliberate ignorance of the truth or falsity of the information provided, or (3) acted with reckless disregard of the truth or falsity of the information provided." 31 U.S.C. § 3729(b)(1)(A)*; see also United States ex rel. Patton* v. *Shaw Servs., L.L.C.*, 418 F. App'x 366, 371 (5th Cir. 2011) ("For FCA liability to attach, not only must the defendant submit false claims, but the defendant must have '***knowingly*** or ***recklessly***' cheated the government").

The Amended Complaint fails to allege any facts sufficient to establish a "knowing" or "intentional" violation of the FCA by ICON, and therefore all claims against ICON must be dismissed. *See, e.g.*, *Sealed Appellant I* v. *Sealed Appellee I,* 156 F. App'x 630, 633 (5th Cir. 2005) (affirming the district court's dismissal of plaintiff's claim because "[t]he complaint include[d] no more than the conclusory assertions of [defendant's] knowledge and intent to file fraudulent claims"). If anything, the Amended Complaint repeatedly suggests that ICON could ***not*** have acted with knowledge, because the alleged violations of regulations and procedures were ***hidden from*** ICON. Relator alleges throughout her pleadings that Ventavia was "not up front" with or otherwise hid information from ICON about the alleged misconduct. (*See, e.g.*, Am. Compl. ¶¶ 150, 157, 161, 169, 176, 178, 183-84, 196, 197, 201, 205, 241, 251 ("Ventavia did not report all clinical trial participants' pregnancies to Pfizer and ICON as required;" "Ventavia did not report this issue to Pfizer or ICON;" "…should have been reported to Pfizer and ICON;" "Ventavia likely falsified informed consent times in order to hide these protocol deviations from Pfizer and ICON;" "Ventavia never reported this violation to Pfizer or ICON;" "Defendant ICON noticed the issue and informed Ventavia. Ventavia falsely told ICON that the discrepancy was due to a transcription error;" "Ventavia also failed to report all adverse events and Serious Adverse Events ("SAEs") to Pfizer and ICON in the clinical trial at issue;"

"Ventavia also did not report many clinical trial protocol deviations to Pfizer and ICON.")). ICON could not knowingly or recklessly cheat the government if the supposed truth allegedly being hidden from the government was ***also*** hidden from ICON.

Relator elsewhere in her Amended Complaint makes conclusory assertions that ICON had "constructive notice" or "constructive knowledge" of purported violations. (*See, e.g.*, Am. Compl. ¶¶ 169, 177, 186, 191, 197 (alleging that ICON "had access to the original source documents in many cases, imparting constructive knowledge of informed consent time discrepancies" and that ICON "had constructive notice of [an] issue because they had access to clinical trial participants' 'electronic diary' entries")). But these conclusory allegations of constructive knowledge are insufficient to establish a knowing violation of the FCA. In order to allege constructive knowledge, Relator must show that ICON "buried [its] head in the sand" and "failed to make simple inquiries which would alert [it] that false claims [were] being submitted." *United States ex rel. Longhi* v. *Lithium Power Techs., Inc.,* 513 F. Supp. 2d 866, 875-76 (S.D. Tex. 2007). Only a "reasonable and prudent" inquiry is required; it is a "limited duty to inquire as opposed to a burdensome obligation." *Id*.

Relator does not allege any specifics about ICON's "constructive" knowledge, including who at ICON was allegedly responsible for reviewing "source documents" or electronic diary entries for the more than 40,000 clinical participants and comparing them to documents provided by Ventavia. *See United States ex rel. Steury* v. *Cardinal Health, Inc.*, 2011 WL 13266915, at *5 (S.D. Tex. 2011), *report and recommendation adopted*, 2011 WL 13266916 (S.D. Tex. 2011) (finding that relator had failed to plead knowledge where "she identifie[d] no Cardinal Health employees who knew that the Signature pumps did not comply with the warranty of merchantability"). More importantly, the exhibits to the Amended Complaint refute any

suggestion that ICON failed to make inquiries or that it "buried its head in the sand." *See supra* Part II.B.

Even assuming that Relator's allegations against ICON are true for purposes of evaluating this motion, the most they assert is that ICON made errors or mistakes in its oversight of Ventavia, but this is far from alleging a knowing violation. Under the FCA, "a lie is actionable but not an error." *United States, ex rel. Johnson* v. *Kaner Med. Grp., P.A*., 641 F. App'x 391, 394 (5th Cir. 2016) (quoting *Riley,* 355 F.3d at 376). "Given this definition of 'knowingly,' courts have found that the mismanagement—alone—of programs that receive federal dollars is not enough to create FCA liability." *Kaner Med. Grp*., 641 F. App'x at 394 (quoting *United States ex rel. Farmer* v. *City of Hous.,* 523 F.3d 333, 339 (5th Cir. 2008)). A finding of negligence or even gross negligence—which Relator again does not adequately allege—is not sufficient "to satisfy the scienter requirement." *Smith* v. *Sanders*, 2017 WL 4536005, at *8 (N.D. Tex. 2017), *report and recommendation adopted*, 2017 WL 4513573 (N.D. Tex. 2017), *aff'd sub nom. United States ex rel. Smith* v. *Wallace*, 723 F. App'x 254 (5th Cir. 2018).

More importantly and decisively for a *qui tam* case, even if Relator had adequately alleged that ICON had knowledge of any alleged violations of trial procedures, this does not establish that ICON had actual knowledge of any material falsity of ***claims made to the government***. *See Steury,* 2011 WL 13266915, at *5 ("[B]ecause the FCA is not a general 'enforcement device' for federal contracts, merely selling defective goods to the government is not enough to create liability. Instead a plaintiff must show that a contractor actually made a false statement to secure payment for the goods.").

CONCLUSION

For the foregoing reasons, in addition to those set forth in Pfizer's Motion, ICON respectfully requests that the Court dismiss the claims asserted against ICON in their entirety with prejudice. ICON also requests oral argument on this motion.

Date: June 6, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 6, 2022, a true and correct copy of the foregoing document was served upon all counsel of record via the Court's CM/ECF system in accordance with this Court's Local Rules.

/s/ Scott L. Davis
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